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BAUM, STUART F

ART UNIT	PAPER NUMBER
1638	b

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/889,926	Applicant(s) XIE ET AL.
	Examiner Stuart F. Baum	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 25 July 2001.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) 2 and 3 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1 and 4-19 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on with application is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____ .

DETAILED ACTION

1. Claims 1-19 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

3. Group I, claims 1 and 4-19 are drawn to an isolated nucleic acid comprising bases 89-1060 of SEQ ID NO:1, transgenic plant and method of growing a genetically altered plant larger than a wild-type plant.

4. Group II, claims 2 and 3 are drawn to a protein consisting of an amino acid sequence of SEQ ID NO:2.

5. The claims are not linked by a single special technical feature because the nucleic acids of Group I are not required for the isolated protein of Group II. The isolated protein of Group II can be made without the expression of the nucleic acid in Group I. For example, the protein can be isolated directly from plants.

Art Unit: 1638

6. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

9. During a telephone conversation with Mike Moran on 7/16/02 a provisional election was made with traverse to prosecute the invention of Group I, claims 1 and 4-19. Affirmation of this election must be made by applicant in replying to this Office action.

Claim Objections

10. Claims 4 and 15 are objected to for depending on a non-elected claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 5-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

To the extent that claim 4 depends from claim 3, the following rejections apply.

In claim 3, replace the word "homologous" with --sequence identity-. The meaning of the word "homologous" includes an evolutionary component, that is not defined.

In claim 3, insert the word --having-- after the first recitation of "protein" to clarify the meaning of the claim.

In claims 5 and 6, the phrase "which is transgenic for a nucleic acid" should be deleted as it does not further clarify the meaning of the claim. In fact, it introduces a redundant phrase.

Claims 7 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: allowing said nucleic acid to be expressed. The omitted step is inserted in the second line, after the number "4".

In claim 7, replace the words "wild-type" with --non-transformed-. All subsequent recitations of "wild-type" are also rejected.

In claim 8, insert --the transcription of-- after the word "wherein".

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: and wherein the expression of NAC1 causes

the plant to grow larger. The omitted steps are inserted in the second line after the second “plant”.

In claim 11, replace the words “said altered” with --a--. The plant is not altered until it has been transformed with said nucleic acid and allowed to grow.

In claims 11 and 15, delete the words “version of said”. The word “version” is indefinite and has not been defined in the specification.

In claims 11 and 15, replace the words “genetically altered” with --transgenic--. It is not clear whether “altered” refers to larger size or to transformation.

In claims 12-14 and 16-18, replace the word “version” with --plant--. The word “version” is indefinite and has not been defined in the specification.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: and wherein the expression of said protein causes the plant to grow larger. The omitted steps are inserted in the second line after the second “plant”.

In claim 15, second line, delete the word “altered”.

In claim 19, replace the word “inserting” with --introducing--.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 4-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleic acid encoding a protein that exhibits at least 70% sequence identity to SEQ ID NO:2, transgenic plant and method of growing a plant. Applicants also claim a method of growing a genetically altered plant comprising overexpressing a NAC1.

The specification only discloses an amino acid sequence of SEQ ID NO:2 (page 5, top paragraph) but does not disclose any specific structural, physical and/or chemical properties for the claimed sequence. Applicants do not present a description of domains that are specific to this particular NAC1 nor domains that are important for its proper function. Applicants also do not define a NAC1, i.e., defining NAC1 to consist of the amino acid sequence of SEQ ID NO:2. Given the lack of description, one skilled in the art would not be able to identify sequences with less than 100% sequence identity that still maintained the proper activity. In addition, given the lack of description for a NAC1, those skilled in the art would not know what sequence constitutes a NAC1. The claims recite a nucleic acid encoding a protein exhibiting 70% sequence identity to SEQ ID NO:2, but Applicant has not disclosed a representative number of species as encompassed by the claims. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The implication is that there is a gene and a protein other than that disclosed which exists in nature, having at least 70% sequence identity to SEQ ID NO:2, but the structure

thereof is not known. Thus, there is insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants and allelic variants from other plants and organisms, absent further guidance. Therefore, the written description requirement is not satisfied. Therefore, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention. (see Written Description Requirement published in Federal Register/Vol.66, No. 4/ Friday, January 5, 2001/Notices; p. 1099-1111).

Enablement

13. Claims 4-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising bases 89-1060 of SEQ ID NO:1 or isolated nucleic acid molecules encoding SEQ ID NO:2 all of which are operably linked to the glucocorticoid-activated promoter (6XUAS_{gal4}) as described by Aoyama et al (1997, The Plant Journal 11:605-612) (page 10, 2nd full paragraph), and plant transformation therewith, to obtain plants with increased mass which was due to thicker leaves, thicker stems and more roots, does not reasonably provide enablement for claims drawn to a nucleic acid encoding a protein exhibiting at least 70% sequence identity to SEQ ID NO:2 including plant transformation therewith to obtain plants with increased mass and Applicant is not enabled for a method of growing a plant, method of growing a transgenic plant and method of growing a transgenic plant larger than a non-transformed plant, all of which comprising transforming a plant with a NAC1, or a nucleic acid encoding a protein exhibiting at least 70% sequence identity to SEQ ID NO:2 and Applicant is not enabled for using any glucocorticoid activated promoter. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *In re Wands* factors (858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to an isolated nucleic acid comprising bases 89-1060 of SEQ ID NO:1, a nucleic acid encoding a protein exhibiting at least 70% sequence identity to SEQ ID NO:2, a transgenic plant or methods of growing a plant or growing a genetically altered plant larger than a non-transformed plant comprising either a nucleic acid encoding a protein exhibiting at least 70% sequence identity to SEQ ID NO:2 or comprising NAC1, respectively.

Applicants isolated a NAC1 cDNA clone from a cell-cycle related screen of *Schizosaccharomyces pombe* expressing cDNA clones from *Arabidopsis*. One transformed *S. pombe* showed elongated cells and multiseptimas. The respective cDNA clone (At012) was found to encode a single open reading frame of 324 amino acids (SEQ ID NO:2) (paragraph spanning pages 4 and 5). The 1287 base pair complete NAC1 encoding cDNA (SEQ ID NO:1) was transformed and expressed in *Arabidopsis* using a

glucocorticoid-inducible transgenic system (page 10, 2nd paragraph). Plants were produced that exhibited an increased mass which was due to thicker leaves, thicker stems and more roots (page 11, lines 13-15).

Applicants' claims are drawn to a nucleic acid sequences encoding a protein exhibiting 70% sequence identity to SEQ ID NO:2, and a method drawn to overexpressing a NAC1 in plants. It cannot be predicted by one of skill in the art if the before mentioned sequences will encode a protein with the same activity as SEQ ID NO:2. Bowie et al (1990, Science 247:1306-10) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of the protein to fold into unique three-dimensional structures that allows it to function and carry out the instructions of the genome. The cited reference also teaches that the prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex (pg 1306, left column). Bowie et al teach that while it is known that many amino acid substitutions are possible in any given protein, the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three-dimensional structure/function relationship, and these regions can tolerate only conservative substitutions or none at all (pg 1306, right column). The sensitivity of proteins to alterations in even a single amino acid in a sequence is exemplified by McConnell et al (2001, Nature 411 (6838):709-713), who teach that the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid

residue, alters the sterol/lipid binding domain. This change renders the protein constitutively active and therefore creates a dominant mutation which has a drastic alteration in phenotype compared to wild-type *Arabidopsis* plants.

Applicant has claims drawn to sequences exhibiting less than 100% sequence identity to SEQ ID NO:2. Because Applicant does not recite a function associated with the sequences, it is not clear if said sequences exhibiting 70% sequence identity to SEQ ID NO:2 would produce the desired phenotype. Specifying that the function of the sequence is to produce "a bigger plant" is not an acceptable function as this is not an assay specific to the particular transcription factor Applicant has isolated. Many other polypeptide encoding nucleic acids also alter the phenotype of a plant in the same manner.

Applicants disclose that NAC1 protein contain a NAC domain (page 2, 1st full paragraph). The state-of-the-art teaches transforming plants with transcription factors that contain a NAC domain produces unpredictable results. Takada et al (2001, Development 128:1127-1135) teach *CUP-SHAPED COTYLEDON1 (CUC1)* gene from *Arabidopsis* possesses a NAC domain and when overexpressed in *Arabidopsis* produces ectopic meristems on the adaxial side of cotyledons and some leaves (page 1132, right column, 3rd paragraph and page 1133, left column, 1st full paragraph).

Applicants' claims are also drawn to nucleic acids that are controlled by any glucocorticoid activated promoter, but the state-of-the-art teaches constructs comprising the hormone-binding domain (BDGR) which is a critical component of the glucocorticoid system produces unpredictable results. Brockmann et al (2001, Plant and Cell Physiology 42(9):942-951) teach a construct comprising the BDGR and GFP (Green

fluorescent protein) was incorrectly and irreversibly targeted to plastids. In addition, Brockmann et al state that "even after 24 hours of [DEX] treatment, only about 1% of all DAPI-stained nucleic accumulated detectable levels of GFP signal in cotyledons. Moreover, in all examined seedlings, large amounts of GFP/Hanf-1/BDGR were still found tightly associated with chloroplasts, notwithstanding the means of DEX application." (page 947, right column, 2nd paragraph).

Given the unpredictability of expressing NAC containing transcription factors in plants for the reasons stated above; given the unpredictability of using any glucocorticoid system for the reasons stated above; given the lack of guidance or examples for using any of the claimed sequences; given the state-of-the-art and the breadth of the claims, it would require undue experimentation to make and/or use the broadly claimed invention.

14. Claim 1 is allowable. SEQ ID NO:1 encoding SEQ ID NO:2 is deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:1 encoding SEQ ID NO:2.

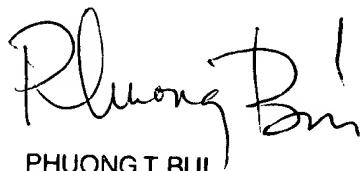
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, who may be contacted at 308-0196.

Stuart F. Baum Ph.D.

April 4, 2003


PHUONG T. BUI
PRIMARY EXAMINER